



Blood Bank of Hawaii

Parent/Legal Guardian Consent Form

Every day, hundreds of lives depend on volunteer blood donors. By giving the gift of life on a regular basis, you help ensure that the blood will be there for Hawaii's patients. The only source for blood is generous volunteers like you!

Common Questions about Blood Donation

Q: Is blood donation safe?

A: Donating blood is safe. All supplies used to collect blood are completely sterile and used only once. You cannot contract HIV or other infectious diseases from donating blood.

Q: Does donating blood hurt?

A: Comfort levels vary from person to person, but most donors say there is nothing to it. You will feel a slight pinch and it is over before you know it.

Q: How long will it take?

A: The entire process takes about 60 minutes, including the interview before and refreshment time after donation. For your safety, you must stay in the refreshment area at least 15 minutes following the donation.

Q: How much can I give?

A: Every donor is evaluated individually with safety in mind. A whole blood donation is about one pint. The exact amount depends on your gender, height and weight.

Blood Donor Qualifications

In general, volunteer blood donors must be 16 or older and in good health.

Whole Blood Height/Weight Restrictions for Donors Age 16-18 Eligibility is based on Estimated Total Blood Volume								
Males between 16 and 18: You must be at least 5' tall and weigh at least 110 pounds								
Females between 16 and 18: If you weigh at least 110 pounds but are shorter than 5'6", refer to chart below:								
Females who are:	4'10"	4'11"	5'	5'1"	5'2"	5'3"	5'4"	5'5"
Must weigh at least:	146	142	138	133	129	124	120	115

The Donation Process

Whole Blood Donation

Blood is collected from an arm vein into a bag specially designed to store blood. Typically, each unit is separated into multiple components, usually red blood cells and plasma. Whole blood donation is the most common way to donate blood.

Apheresis Donation

Apheresis is an automated procedure that is used to collect blood products (platelets, plasma, and red blood cells) from your blood. During apheresis, your blood is circulated through a cell separator that collects only the product(s) that are needed and returns the rest of the blood to you. During Apheresis collections, a small amount of anticoagulant (citrate) is added to the donor's blood to prevent clotting during

the procedure. Donors may also receive normal saline as part of the apheresis collection procedure. Qualified collection staff members closely monitor the entire Apheresis process.

Some Potential Side Effects

Donating blood removes iron from the body. Frequent blood donors may become iron deficient despite having an acceptable hemoglobin level. A multivitamin or iron replacement between donations may reduce the risk of iron deficiency. Serious complications are rare. However, as in any medical procedure, there are certain risks. Potential side effects include nausea, dizziness, lightheadedness, pallor, fainting, bruising, or swelling of the arm from which blood was drawn. On rare

Some Potential Side Effects...continued

occasions, more severe reactions with long-term complications may occur, such as infection or nerve damage. Other possible complications include fatigue, decreased exercise tolerance for three to five days and, very rarely, allergic reaction, shortness of breath, chest pain, and decreased blood pressure. While a small percentage of blood donors have adverse reactions, donors aged 16 to 18 do experience a higher prevalence of reactions. To reduce the likelihood of a reaction, the blood center evaluates eligibility for younger donors based on weight and height

to determine blood volume. The chart on the previous page indicates whether your blood volume is sufficient for you to donate.

Apheresis donations may have additional adverse consequences, including but not limited to symptoms of low calcium (numbness or tingling around the mouth or in your fingers, cramps, stiffness) for which you may be given oral calcium replacement, feeling of warmth, chills, allergic reactions, shortness of breath, chest pain, decreased blood pressure, or air embolism.

Parents/Legal Guardians: Help the donor have a good donation experience.

The day before donation: Make sure the donor eats a salty snack, like chips or pretzels, and has a meal that is higher in sodium, such as fast food, canned soup, pizza, etc. Some sodium is lost during donation. Replacing some of that sodium ahead of time makes donors thirsty. Drink 8-10 glasses of fluids. Being well-hydrated helps donors maintain blood volume and can prevent dizziness or fainting.

The day of donation: Make sure the donor has a hearty meal before donating, and encourage the donor to carefully follow our directions.

Safety of both the blood donor and the patient receiving the blood is of the utmost importance. Each blood donation is performed by trained professionals and includes:

- A mini-physical to ensure blood pressure, temperature, pulse, and hemoglobin count are within established parameters to safely donate blood.
- A confidential interview with our Collections staff to review each donor's medical and travel history, potential exposure to infectious diseases and the opportunity to ask questions and receive counseling regarding the donation process and related testing.
- Collection of the blood which takes just five to eight minutes on average.
- A brief rest on the donor bed and refreshments following donation to help recover and replenish fluids.
- A sample from each blood donation will be tested for HIV (AIDS), HTLV, hepatitis, syphilis, and other infectious agents as required by regulations. Abnormal test results are confidential and unless required by law, will only be reported to the donor.

Our blood center participates in research to improve blood safety. We may use your donor history information and a sample of your blood, in a confidential manner, for blood safety research, as described in the accompanying research information document(s). We are required to get parental consent for both 16 and 17 year old donors for this research.

If you have any questions about the blood donation process, please call the Collections Department of Blood Bank of Hawaii at 845-9966 (Oahu) or 800-372-9966 (Neighbor Islands). On behalf of the patients we serve, we thank you for your support of your teenager's wish to selflessly save lives in Hawaii.

Please be sure that you and the donor have read the information provided.

I give my permission for my minor donor to donate and for that donation to be tested as explained above.

The following must be completed in blue or black ink.

_____ Parent/Legal Guardian Name (Please Print)	_____ Signature of Parent/Legal Guardian	_____ Date
_____ Minor Donor's Name (Please Print)	_____ On day of donation, I can be reached at this phone number	

Zika Virus Research Information

Sponsor / Study Title: Hologic, Inc. / Pre-pivotal Procleix® Zika Virus Assay Testing of Donations From Donors of Whole Blood and Blood Components

Protocol Number: B10383-ZIKVPS-CSP-01

Principal Investigator: Phillip Williamson, Ph.D.

Telephone: 866-342-4275 ext. 7197

Additional Contacts: Randal Covin, M.D. 808-848-4771

Please read this form carefully. Take time to ask the donor center staff as many questions about the use of your blood for research studies as you would like. The donor center staff can explain words or information that you do not understand. Reading this form and talking to the donor center staff may help you decide whether to donate or not.

You are being asked to participate in a research study to evaluate a new test for detection of a mosquito-borne agent known as Zika virus. Zika is a virus that rarely causes paralytic nervous system damage, but in pregnancy, can cause loss of the baby or serious birth defects. Most people do not get sick after infection. Only one in five people will have fever, rash, joint pain, and conjunctivitis (red eyes) lasting a few days to a week. Zika is usually transmitted by the bite of an infected mosquito. It can also be transmitted by sex with an infected person, from a pregnant mother to her baby and by blood transfusion.

This donor center is doing a research study to understand the effectiveness of new tests to detect Zika virus in donated blood and prevent patient exposure. Some of this research is conducted with other institutions, such as blood bank organizations, academic centers and biomedical companies. Any remainder of your donation may be stored up to 3 years after the completion of the study and used for further research related to the Zika virus.

Samples linked to your identifying information will be tested for ZIKA virus. If your test results suggest that you may be infected, this donation center will attempt to contact you to notify you and explain the significance of the results. The donation center will discuss the potential risk for sexual transmission of Zika Virus, and potential harm to the fetus during pregnancy. You will be notified in person, by phone, or by letter. If your test results suggest that you may be infected, you should discuss these results with your primary care physician. You may also visit the Centers for Disease Control and Prevention (CDC) website at <http://www.cdc.gov/zika/> for additional information regarding Zika virus.

If the results suggest that you may have a Zika virus infection, you will be invited to participate in voluntary follow-up studies involving additional blood samples. Should you choose to participate, additional informed consent process will be required.

Your participation in this research study is entirely voluntary. You will not be paid for your participation in this study. Your participation will not require any additional procedures or time beyond the normal donation process. The risk of having your donation tested with the study test is not any greater than having your donation tested for other infectious diseases, although a positive result may alarm you. There is a very low chance that your blood sample may give a false positive result. If the test is positive, the blood that you donate will not be used for transfusion. There will be no costs or payments to you for your participation in this study. Although you may not receive a direct benefit from this study, the results may allow for better test systems to become available to protect the blood supply.

The results of all testing on your donation during this study are confidential, except when reportable by

Zika Virus Research Information

law to public health authorities, and to authorized blood center personnel, the U.S. Food and Drug Administration (FDA), Hologic, Inc. and associated Zika studies. Your age, gender, general geographic location, and test results may be used to evaluate important information about Zika virus, but this information is combined with information about other donors and not identified with you.

You may refuse to participate by notifying the blood collection staff that you will not be donating blood or blood components today. If you decline testing we will be unable to use your whole blood or red blood cells, however, we will inform you whether you may donate plasma or platelets. If you decide not to participate at this time, your decision will not change your future relationship with the blood center and there is no penalty to you. If you decide not to participate after your donation is taken, call the Principal Investigator at the number(s) above.

An Independent Review Board (IRB) is a group of people who review research studies to protect the rights and welfare of research participants. If you have questions or complaints about your rights as a study participant contact the Chesapeake IRB:

- By mail:
Study Subject Adviser
Chesapeake IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free:** 877-992-4724
- or by **email:** adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00017603.

If you have scientific questions or questions about your participation in these studies, you may contact our Donor Counseling Service at **808-845-9966, 6:30 am to 4:30 pm. By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and associated information for research purposes related to Zika virus.**